Remarks

By way of this amendment, claims 1-8, 12 and 13 are pending in the application. Claims 1, 7 and 12 have been amended. Claim 13 has been added. No new matter has been added by way of these claim amendments and additions.

Section 103(a)

The rejection of claims 1-8 and 12 under 35 U.S.C. § 103(a) as being obvious in light of Jenkins (EP 0 205 282) or Jenkins (US 4,940,587) is maintained.

Overall, the pharmaceutical compositions and processes described in Jenkins differ significantly in purpose and effect from those of the instant invention. Jenkins describes pharmaceutical compositions containing a granulated mixture of an aliphatic alcohol, a hydroxyalkly cellulose and a pharmaceutical. This mixture is then coated with another hydroxyalkyl cellulose before being compressed into a solid unit dosage form. The coating of the compositions in Jenkins is to promote the adherence of the solid unit dosage form to the buccal mucosa, where it remains as a whole as it slowly dissolves and thereby releases drug. The compositions and processes described in Jenkins are for use primarily in buccal administration of drug. Therefore, agitation independence is not a factor for the administration route of Jenkins. As a matter of fact, such agitation independence would thwart the basis for the invention of Jenkins since it would circumvent the sustained release feature of the invention of Jenkins.

In contrast, the pharmaceutical compositions of the instant application contain only a granulated mixture of hydroxypropylcellulose and pharmaceutical without the alcohol. Additionally, the granulated mixture of hydroxypropylcellulose and pharmaceutical is not coated, as required by Jenkins, because the compositions of the instant application do not need to adhere to the buccal or nasal mucosa. Furthermore, the compositions of the instant application are not compressed, as also required by the processes described in Jenkins, because a multi-unit, agitation-independent dosage form

is desired. More specifically, the particles in the instant invention may be lacquered to prevent agglomeration, which is counter to the effect taught by Jenkins. The granules of the instant invention are contained by a suitable vehicle, such as a capsule, for instance, that, upon oral ingestion, releases the individual particles to provide a multi-unit dosage form that administers drug in an agitation-independent manner.

The difference between compressing the granules into a tablet, as described by Jenkins (see col. 5, l. 12-14 and claim 17), and filling capsules or other suitable delivery vehicles with loose granules is the primary difference between the process of Jenkins and that of the instant application. The process of compressing the granules in Jenkins is for creating the solid unit dosage form, whereas the process of the instant application is for creating a multi-unit, agitation-independent dosage form. Applicants have amended claims 1 and 12 to more clearly define the process and pharmaceutical composition as a capsule containing the particles of drug and hydroxypropyl cellulose. Applicants submit that claims 1-8 and 12, as amended, are allowable under 35 U.S.C. § 103(a) over either of the Jenkins references.

Conclusion

Applicants respectfully submit that the pending claims are in condition for allowance. Reconsideration is respectfully requested. Please charge any fees due with this amendment to deposit account number 13-3372. If the Examiner believes that a conversation with Applicants' attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned attorney at (203) 812-3964.

Respectfully submitted,

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